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| APPLICATION NO. | FI | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---|-----------------|------------|----------------------|----------------------|-----------------|
| 10/047,072 | ,072 01/15/2002 | | Ralph M. Steinman | MER-011CN/112917-144 | 7452 |
| 43852 | 7590 | 05/19/2006 | | EXAMINER | |
| MERIX BI | | - | EWOLDT, GERALD R | | |
| 4233 TECHNOLOGY DRIVE DURHAM, NC 27704 | | | | ART UNIT | PAPER NUMBER |
| | | | | 1644 | |

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | |
|---|---|--|--|--|--|--|--|
| | | 10/047,072 | STEINMAN ET AL. | | | | |
| | Office Action Summary | Examiner | Art Unit | | | | |
| | | G. R. Ewoldt, Ph.D. | 1644 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHO WHIC - Exter after - If NO - Failui Any r | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATES as a soint of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. It period for reply is specified above, the maximum statutory period vere to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONEI | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | | |
| 2a)□ | Responsive to communication(s) filed on <u>28 Fe</u> This action is FINAL . 2b) This Since this application is in condition for allowar closed in accordance with the practice under E | action is non-final. nce except for formal matters, pro | | | | | |
| Dispositi | on of Claims | | | | | | |
| 5)□ 6)⊠ 7)□ | Claim(s) <u>1-6 and 10-12</u> is/are pending in the appear of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) <u>1-6 and 10-12</u> is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or | vn from consideration. | | | | | |
| Applicati | on Papers | | | | | | |
| 10)□ | The specification is objected to by the Examine The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Example 2. | epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | | | |
| Priority L | ınder 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 2) Notice 3) Information | t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | | | | | |

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DETAILED ACTION

1. In view of Applicant's amendment, filed 2/28/06, all previous rejections and objections have been withdrawn.

- Claims 1 and 5 have been amended.
 Claims 1-6 and 10-12 are being acted upon.
- 3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP \S 608.01(o). Correction of the following is required:
- A) The list of cytokines employed in the methods of Claims 6 and 10 has no antecedent basis in the specification.

The specification must be amended to include said limitations.

- 4. The following are new grounds of rejection.
- 5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 6 and 10 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

Regarding Claim 6, the method of the claims as originally presented recited a single step method. Claim 1, from which Claim 6 depends, now recites a multi-step method. The use of the cytokines of Claim 6 in the second step, i.e., as the "composition" (which is employed only in the second step), is not disclosed in the specification.

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Regarding Claim 10, a specific range of concentrations of GM-CSF is disclosed in the specification at page 16 as being used in the first step, i.e., the production of immature DCs, and not in the second step, i.e., as the "composition" of Claim 6 (from which Claim 10 depends).

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7. Claims 1-6 and 10-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of the generic, i.e., from any source, cytokines, e.g., GM-CSF, IL-4, IL-13, TNF- α , of Claims 1, 5, 6, and 10.

The specification discloses in a generic sense, i.e., the sense of the claims, only the use of specific cytokines, e.g., GM-CSF, IL-4, IL-13, of unknown sources. In the examples numerous human cytokines, e.g., GM-CSF, IL-4,, IL-6, IL-13, stem cell factor, etc., including some recombinant cytokines, e.g., rh-IL-4, are disclosed. The method of the claims, however, would encompass the use of cytokines from any sources, e.g., baboons to wombats, cytokines clearly not adequately described in the instant specification. One of skill in the art would conclude therefore that the specification fails to disclose a representative number of species to describe the genus of specific cytokines employed in the method of the instant claims. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

- 8. No claim is allowed.
- 9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from

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7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

10. Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.

G.Ŕ. Ewoldt, Ph.D. Primary Examiner

Technology Center 1600